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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,285	01/15/2001	Nicholas C. Nicolaides	MOR-0017	2664

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT

PAPER NUMBER

1632

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,285

Applicant(s)

NICOLAIDES ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Election/Restriction (Group and Species Restriction)

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-13, 22, drawn to a method of making a hypermutable cell wherein an anthrancene is employed as an inhibitor of mismatch repair, classified in class 552, subclass 209.

Group II. Claims 1, 14, 22, drawn to a method of making a hypermutable cell wherein an ATPase inhibitor (AMP-PNP) is employed as an inhibitor of mismatch repair, classifiable in class 435, subclass 184.

Group III. Claims 1, 15, 22, drawn to a method of making a hypermutable cell wherein a nuclease inhibitor is employed as an inhibitor of mismatch repair, classifiable in class 424, subclass 178.1

Group IV. Claims 1, 16, 22, drawn to a method of making a hypermutable cell wherein a polymerase inhibitor is employed as an inhibitor of mismatch repair, classifiable in class 414, subclass 146.1

Group V. Claims 1 and 17-22, drawn to a method of making a hypermutable cell wherein an antisense DNA is employed as an inhibitor of a mismatch repair protein encoded DNA, classifiable in class 514, subclass 44.

Group VI. Claims 23, 24, 27-29, 68, 70, drawn to a method of generating a mutation in a gene of interest comprising administering to an *in vitro* cell a chemical mismatch repair inhibitor and the step of DNA analysis, classifiable in class 435, subclass 6.

Group VII. Claims 23, 25, 27, 28, 30, 68, 70, drawn to a method of generating a mutation in a gene of interest comprising administering to an *in vitro* cell a chemical mismatch repair inhibitor and the

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step of protein analysis, classifiable in class 435, subclass 7.1.

Group VIII. Claims 23, 26, 27, 28, 31, 68, 70, drawn to a method of generating a mutation in a gene of interest comprising administering to cell *in situ* or *in vitro*, a chemical mismatch repair inhibitor and the step of phenotype analysis, classifiable in class 800, subclass 3.

Group IX. Claims 23, 24, 27-29, 32-34, 68-70, drawn to a method of generating a mutation in a gene of interest comprising administering to an *in vivo* animal cell or animal a chemical mismatch repair inhibitor and the step of DNA analysis, classifiable in Class 514, subclass 44, class 435, subclass 6.

Group X. Claims 23, 25, 27, 28, 30, 32, 33, 35, 68-70, drawn to a method of generating a mutation in a gene of interest comprising administering to an *in vivo* animal cell or animal a chemical mismatch repair inhibitor and the step of protein analysis, classifiable in class 514, subclass 44, 435, subclass 7.1.

Group XI. Claims 23, 26, 27, 28, 31, 32, 33, 36, 68-70, drawn to a method of generating a mutation in a gene of interest comprising administering to an *in vivo* animal cell or animal a chemical mismatch repair inhibitor and the step of phenotype analysis, classifiable in class 514, subclass 44.

Group XII. Claims 41, 42, 45, drawn to a method of generating a mutation in a gene of interest comprising growing a plant, and administering to the plant a chemical mismatch repair inhibitor and the step of DNA analysis, classifiable in class 800, subclass 270.

Group XIII. Claims 41, 43, 45, drawn to a method of generating a mutation in a gene of interest comprising growing a plant, and administering to the plant a chemical mismatch repair inhibitor and the step of protein analysis, classifiable in Class 800, subclass 267, class 435, subclass 7.1.

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Group XIV. Claims 41, 44, 45-48, drawn to a method of generating a mutation in a gene of interest comprising growing a plant, and administering to the plant a chemical mismatch repair inhibitor and the step of phenotype analysis, classifiable in class 800, subclass 266.

Group XV. Claims 49-50, 53-55, 71, drawn to a screening method comprising using a candidate compound in a mammal, classifiable in Class 514, subclass 44.

Group XVI. Claims 49, 51, 53-55, 71, drawn to a screening method comprising using a candidate compound in a microbe, classifiable in Class 435, subclass 7.2.

Group XVII. Claims 49, 52, 53-55, 71, drawn to a screening method comprising using a candidate compound in a plant, classifiable in Class 800, subclass 276.

Group XVIII. Claims 56-67, 71, drawn to a method of blocking mismatch repair in a cell *in vivo* by administering to the cell an anthracene compound, classifiable in class 552, subclass 209

Claims 23, 27, 28, 30, 68, 70 link inventions VI-XI. Claims 41, 45 link inventions XII-XIV. Claims 49, 53-71 link inventions XV-XVII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

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requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

1/ As set forth in MPEP 803.02, unity of invention for exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Claim 1, for example, does not have unity of invention because an anthracene, an ATPase inhibitor, a nuclease inhibitor and a polymerase inhibitor do not share any common structure with one another.

2/ Since the claims do not have the unity of invention, groups I-V are distinct because

The Methods cited in the groups are directed to materially distinct steps that render the methods patentably distinct with respect to their functions and their sites of action, particularly in view of the foregoing reasons.

In addition, Inventions I-XVIII are directed to distinct goal and comprise materially distinct steps, whereby distinct functions and effect are generated, and further, a search of one invention does not necessarily overlap with that of another group.

Should Group I or Group XVIII be elected, the claims of the respective group are generic to a plurality of disclosed patentably distinct species comprising:

A specifically name species of compound selected from claim 3-13 or from claims 57-67, wherein a specifically name combination of identifiers must be specified and elected, and wherein each identifier from the elected combination must be specified and elected.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed

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above and cited in the claims, even though this requirement is traversed.

Should any of Groups VI-XI be elected, the claims of the respective group are generic to a plurality of disclosed patentably distinct species comprising:

A specifically name species of mutagen as recited in claim 70.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above and cited in the claims, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and because of an enormous number of compounds as claimed for their respective utility(ies), an undue burden to examine for patentability is required, and therefore, the restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b)

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and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388**.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER